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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/658,302	09/08/00	BATEMAN	P 49447-2USPX

P. WESTON MUSSelman JR  
JENKENS & GILCHRIST PC  
SUITE 3200  
1445 ROSS AVENUE  
DALLAS TX 75202-2799

HM22/0523

EXAMINER	
PADMANABHAN, K	
ART UNIT	PAPER NUMBER
1641	8
DATE MAILED:	05/23/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/658,302	BATEMAN, PAUL	
	Examiner Kartic Padmanabhan	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 26 September 2000.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-4, 6-10, 12-31 and 45 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-4, 6-10, 12-31 and 45 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

15) Notice of References Cited (PTO-892)

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.

18) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

19) Notice of Informal Patent Application (PTO-152)

20) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Priority***

1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The second application (which is called a continuing application) must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the continuing application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *In re Ahlbrecht*, 168 USPQ 293 (CCPA 1971).

Since a copy of the parent application was not provided, there is no way to ascertain if the disclosures of the two applications are the same, thus entitling applicant to priority.

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the United Kingdom on August 14, 1998. It is noted, however, that applicant has not filed a certified copy of the UK application as required by 35 U.S.C. 119(b).
3. If applicant wishes to obtain the benefits of a foreign filing date under 35 U.S.C. 119(a)-(d), applicant should also file a claim for such priority as required by 35 U.S.C. 119(b).

### ***Information Disclosure Statement***

4. The reference, FR2614899, was not considered, as it was not in the English language, and no statement of relevance was provided.
5. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be

incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

***Specification***

6. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 10, 12, 14-16, 19-24, 27, and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481

(Bd. App. 1949). In the present instance, claim 10 recites the broad recitation of a filter thickness of 200-1000uM, and the claim also recites 400-800Um and 600uM, which are the narrower statements of the range/limitation.

10. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 12 recites the broad recitation of a retention size of 5-100uM, and the claim also recites 8-60uM and 10-40uM which are the narrower statements of the range/limitation.

11. Claims 14 and 15 are rejected for the recitation of the term "capable". It is unclear if the reagents of claim 14 generate a signal or not, just as it is unclear if the antibodies of claim 15 bind spermatozoa.

12. Claim 16 is rejected for the recitation of "can be" for the same reason as applied to "capable" in claims 14 and 15. Applicant should also correct the spelling of "immobilised".

13. Claim 19 is rejected as vague and indefinite for the recitation of "capable" for reasons previously discussed.
14. Applicant should correct the spelling of "labelled" in claims 21 and 22.
15. Applicant should change the spelling of "recognise" in claims 23 and 24 to "recognize".
16. Claim 27 recites the limitation "the calcium ionophore A24297" in line 12. There is insufficient antecedent basis for this limitation in the claim.
17. Claim 29 is rejected as vague and indefinite for the recitation of "capable" for reasons discussed above.

***Claim Rejections - 35 USC § 102***

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

19. Claims 1-4, 6-10, 12-31, and 45 are rejected under 35 U.S.C. 102(a) as being anticipated by Barratt (WO 99/66331).

Barratt discloses an apparatus and method for separating motile spermatozoa from non-motile spermatozoa comprising a vessel having an inlet and outlet with a filter disposed therebetween. The filter, whoosh may be made of gel, foam, glass wool, or polypropylene, allows passage of motile sperm, but not the rest of the sample. The apparatus further comprises

a spermatozoa detection means on the outlet side of the filter, wherein the detection means is integral to the apparatus, but may be separable. The filter of the apparatus has a thickness of 25 to 2500  $\mu\text{M}$ , with a pore size of 5-100 $\mu\text{M}$ . The filter may be supported on either or both sides of the porous layer, by means of a plastic backing. The detection zone of the apparatus preferably comprises a combination of reagents, such as antibodies, which generate a visual signal on interaction with spermatozoa. The spermatozoa, when immobilized by the antibodies, can be detected using a detectable signal that binds to the spermatozoa. The apparatus of the invention may also comprise chemoattractant in the detection means. The invention of the reference further comprises a pick up zone comprising reagents, such as labeled antibodies, capable of binding spermatozoa and being transported to a detection area. The antibodies may be labeled with gold particles. The antibodies located in the detection area may recognize the same or different spermatozoa antigens compared to the antibodies located in the pick up zone. The detection means of the device may also comprise an acrosome lysing reagent and a means for detecting pH change. The acrosome-lysing reagent is preferably lysis buffer comprising proteinase K or A23187, and the pH detection means can be a pH indicator such as bromocresol purple or a pH sensitive probe. According to the reference, the device can also comprise a spermatozoa-liquefying reagent on the filter. The reference further includes means for supplying fluid to the opposing surface of the filter means, as simply putting a sample containing spermatozoa on one side of the filter meets this limitation, as the filtered sample must pass through the filter, which would place the opposing side of the filter in contact with a liquid.

20. Claims 1, 3-4, 6, 12, 14-16, 19-22, 31, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Alvarez (WO 96/13225). Alvarez discloses assays, kits, and devices for

determining male fertility wherein motile sperm can be isolated from a sperm-containing sample, such as semen. According to the reference, a relatively dense sperm containing sample can be contacted with a less dense fluid layer, including a first fluid layer and a porous membrane, which is mounted on a liquid reservoir. The first fluid layer may include a reagent for liquefying the semen sample. The membrane allows motile sperm to pass through while preventing flow of the sample. The membrane can be composed of any suitable biocompatible material, such as nitrocellulose or glass wool. The pore size may be around 5 $\mu$ M. After a certain amount of time, a sample of motile sperm is removed and introduced into a test tube holding test reagents comprising antibodies, which may be labeled with particles such as gold. A test strip containing antibodies is contacted with the solution, and then contacted with a peroxidase solution. The test strip changes color to indicate the presence of motile sperm. An inlet and outlet are inherent as they are simply interpreted as areas where the sample enters and exits the filter, respectively.

21. Claims 1, 3-4, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Jeyendran (US Pat. 5,575,914). Jeyendran discloses a filter trap for removing spermatozoa of low viability and other extraneous material from a fluid and allowing high viability spermatozoa (motile) to flow through, where the motile spermatozoa can then be detected. The device of the reference comprises a conduit comprising silica glass wool as the filter material. The device has an inlet, and a filtered outlet, with the filter material disposed between the two (fig. 5). As the sample, fresh ejaculate can be used, as long as it is first allowed to fully liquefy. Since the sample is applied to a first surface of the filter means, it is inherent that the sample, upon passing through the filter, will also contact the opposing surface of the filter, thereby meeting the limitation of a means for supplying fluid to the opposing surface of the filter.

22. Claims 1 and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Zavos (US Pat. 5,976,389). Zavos discloses a method and device for semen filtration comprising admixing Sephadex beads in the column of a filtering device having opening at both ends with a media. The multilayer filter will allow the passage of motile spermatozoa, which can then be recovered. The semen for use with the device must first be liquefied.

23. Claims 1, 3, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Bar-Ami et al. (US Pat. 6,129,214). Bar Ami et al. disclose a sperm strainer system which filters motile sperm from a semen sample using a nucleopore membrane, which can be made of nylon, with a pore size of 5-8 microns. The sperm sample is placed on one side of the membrane, and the motile sperm migrate through the membrane, and leave the non-motile sperm and other extraneous materials behind. The nucleopore membrane has first and second opposing surfaces, both of which will be contacted with a liquid medium, as the sample portion containing the motile sperm will contact both surfaces as it flows through the filter. An inlet and filtered outlet means are inherent in the device of the reference.

***Claim Rejections - 35 USC § 103***

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

25. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

26. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jayendran (US Pat. 5,575,914).

Jayendran teaches a semen filtration device, as discussed above. However, the reference does not teach the use of an enzyme liquefaction reagent on the surface of the filter.

It would have *been prima facie* obvious to one of ordinary skill in the art at the time of the invention to use a liquefaction reagent with the device of Jayendran. Since the device of the reference requires sperm liquefaction before filtration, placing a liquefaction reagent on the surface of the filter would save considerable time, as both functions could be carried out almost simultaneously with the same device.

### ***Conclusion***

Claims 1-4, 6-10, 12-31, and 45 are rejected.

References: Benjamin et al., Ellington et al., Sanchez et al., Agarwal et al., Robertson et al., Bucalo, Bergman et al., Kricka et al., Deutsch, Wang, and Ericsson are cited as art of interest for teach various filtration and detection methods and devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the

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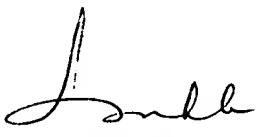
organization where this application or proceeding is assigned are 703-308-4243 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan  
Patent Examiner  
Art Unit 1641

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May 21, 2001

  
LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

05/21/01